IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

United States of America, ex rel. Terry Jackson	:	CIVIL ACTION NO. 15-020
Plaintiff,	:	
v.	:	
DePaul Health System, et al.,	:	
Defendants.	:	

M E M O R A N D U M

EDUARDO C. ROBRENO, J. April 15, 2020

I. INTRODUCTION

Terry Jackson brings a qui tam action against Baker's Bay Nursing Home Associates, LP, and DePaul Healthcare, LP, for violating the False Claims Act by allegedly providing worthless services to its nursing home residents and submitting falsified forms to the government. Before the Court are Defendants' motion in limine and motion for summary judgment.

Jackson's evidence of regulatory noncompliance does not show the level of malfeasance required to prove a factually false claim based on a worthless services theory. On the other hand, Jackson does point to enough evidence of the submission of inaccurate forms to raise a genuine issue of material fact about the submission of a legally false claim based on an express certification theory.

Therefore, for the reasons set forth below, the motions will be granted in part and denied in part.

II. FACTUAL BACKGROUND

Defendants operate River's Edge, a 120-bed nursing facility that provides short- and long-term care to between 60 and 120 residents. To provide care to these residents, it employs Certified Nursing Assistants ("CNA"), Licensed Practical Nurses ("LPN"), Registered Nurses ("RN"), and Primary Care Physicians. Patient care and regulatory compliance is overseen by a Director of Nursing ("Director"). River's Edge receives payment for the services it provides to its residents through private pay, commercial insurance, and Medicaid and Medicare.

A. River's Edge's Regulatory Compliance

As a recipient of Medicare and Medicaid funds, River's Edge is required to submit to the federal government Minimum Data Set ("MDS") forms for each resident annually, quarterly, and if there is a significant change in a resident's condition.[1] MDS forms contain resident information, such as whether a resident fell or experienced excess weight loss. But the MDS forms do not contain all the data from a resident's file. Instead, the

[1] This information is collected by Centers for Medicare & Medicaid Services ("CMS"), which is an agency in the Department of Health and Human Services. See 42 C.F.R. §§ 483.20, 483.315.

Director collects data from Activities of Daily Living ("ADL") forms, which are filled out by CNAs, and translates this information into the MDS forms. MDS forms also include a certification that the information contained in the form is accurate and that the payment of federal funds is conditioned on the accuracy of the form. River's Edge is then paid per resident per day based on the information contained in each resident's MDS form.

River's Edge is also required to comply with a Pennsylvania regulation requiring a minimum of 2.7 hours of care per patient per day ("PPD"). 28 Pa. Code § 211.12. Compliance with this regulation is based on the total actual hours worked by staff in a 24-hour day divided by the number of residents. And compliance is tracked by a staffing coordinator and monitored by the Director. River's Edge creates a four-to-six-week schedule and a projected PPD based on this schedule. Then, it creates a daily staff assignment sheet based on the schedule and the number of residents for each day. Last, the actual PPD is calculated by looking at the payroll records and the daily assignments.

River's Edge's operations are audited by the Pennsylvania Department of Health through unannounced visits. At these visits, which last several days, the Department of Health

announces to the residents that they should share with the Department their complaints about the facility. Despite these unannounced visits, between 2012 and 2017 the Department of Health did not find any aspect of River's Edge operation to be "immediate jeopardy" deficient,[2] and River's Edge was never ordered to shut down. That said, the Department of Health issued two statements of deficiencies for River's Edge in 2015: (1) failure to accurately complete seven MDS forms and (2) failure to properly submit Electronic Event Reports[3] for a scabies outbreak for twelve residents.

In addition to the unannounced regulatory audits, River's Edge independently ensures regulatory compliance. To ensure compliance with standard of care regulations, the Director performs daily rounds and conducts monthly resident council meetings. And to ensure compliance with the PPD regulations, River's Edge schedules its staff to work more than the minimum required hours, such that there is a surplus in excess of the required 2.7 PPD, to account for staff call outs and no shows.

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[2] The Department of Health inspects various departments, e.g., nursing, and provides the facility with a list of deficiencies ranging from D, which is paper noncompliance, to IJ or immediate jeopardy, which is widespread danger.

[3] Under Pennsylvania regulations, nursing homes are required to report various events, e.g., a scabies outbreak, through Electronic Event Reports. 28 Pa. Code § 211.1.

B. Terry Jackson

Terry Jackson, the plaintiff or relator in this case, worked at River's Edge part-time as a CNA from 1999 to 2014. As a CNA, her job was to assist nurses in caring for patients and to fill out ADL forms. Jackson was never involved with (1) billing Medicaid or Medicare, (2) scheduling or calculating PPD, (3) procurement of supplies, or (4) Department of Health inspections. Nonetheless, Jackson alleges that during her time at River's Edge, the facility was understaffed, provided substandard care to its residents, and must have submitted fraudulent compliance forms to the federal government.

Jackson alleges that River's Edge was so understaffed that nurses could not respond to residents' call-bells and could not provide adequate care. According to Jackson, while each nursing staff member should have been assigned 12 residents to comply with the PPD regulation, they were typically each assigned between 14 and 16 residents. She was present for three Department of Health inspections in her 15 years at River's Edge, and she claims that the facility changed staff schedules during inspections to ensure that there was enough staff during the inspections. She also alleges that bed-ridden residents were left in unsanitary conditions, including being left in soiled sheets without being bathed, due to staffing shortages.

And she alleges that LPNs performed tasks that only RNs were certified to perform. Further, Jackson describes a lack of proper equipment, such as clean towels and linens. But at the same time as she makes all of these allegations, she acknowledges that the care she provided was fair, good, or excellent.

Jackson claims there were fraudulent representations in the MDS forms submitted for Medicare and Medicaid reimbursement because the ADL forms that she completed contained errors. Jackson completed ADL forms weeks after giving the care being documented due to her having insufficient time to complete the forms at the same time as rendering the care. So, although she was never told to falsify ADL forms, she asserts that the delay in completing the forms inevitably led to errors, which in turn necessarily caused false representations in the MDS forms because the MDS forms are prepared based on information in the ADL forms. Jackson also alleges that some services recorded in River's Edge's MDS forms never actually occurred. But she does not point to any specific error in an ADL form or misrepresentation in an MDS form.

C. D.F., W.M., and C.D.

Jackson provides four examples—three specific and one non-specific—of low-quality care at River's Edge. Most of Jackson's

allegations of substandard care are devoid of specifics. Her assertion that a resident had a maggot-infested wound does not include the resident's name or the time frame of this incident. But Jackson does point to, as representative examples of poor care, circumstances allegedly constituting substandard care to three residents.

First, D.F. had scabies, a highly contagious skin condition, which was treated for two weeks with a cream to relieve symptoms. Jackson contends that D.F.'s treatment should have been more than just application of symptom-relief cream. But she does not present evidence of a more appropriate treatment, and River's Edge contends that the treatment provided was adequate. D.F. was also not quarantined, which led to an outbreak of scabies. River's Edge did not report the outbreak, but it has subsequently implemented procedures to ensure the reporting of infection outbreaks in the future.

Second, W.M. suffered from bedsores and was not always turned every two hours, as required for bedsore treatment, because of a lack of staffing. According to Jackson, the extent of the substandard care was that she sometimes failed to turn W.M. every two hours. And W.M. was treated by a wound care specialist.

Last, C.D., a ninety-year-old resident in a wheelchair, was left unattended and suffered a fall that resulted in severe injuries. C.D. was on the ground for twenty minutes after the fall because River's Edge staff chose not to move her given the extent of the injuries and the risk of exacerbating the injuries. They called an ambulance instead. As a result of the fall, C.D. lost the mobility that she had prior to the fall.

D. Procedural History

Jackson's complaint consists of two counts: (1) False Claims Act and (2) retaliation. Upon investigation of Jackson's allegations, the United States declined to intervene in the action. Defendants moved to dismiss for failure to state a claim. And the Court granted Defendants' motion in part, dismissing Jackson's retaliation count but allowing her False Claims Act count to proceed on both a worthless services theory and a false certification theory.

Now, Defendants move for summary judgment, arguing that the record shows the services provided were not worthless and that Jackson fails to point to evidence of a false material certification. Together with the motion for summary judgment, Defendants move to exclude the testimony of Jackson's expert.

III. LEGAL STANDARD

Summary judgment is appropriate if there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). "A motion for summary judgment will not be defeated by 'the mere existence' of some disputed facts, but will be denied when there is a genuine issue of material fact." Am. Eagle Outfitters v. Lyle & Scott Ltd., 584 F.3d 575, 581 (3d Cir. 2009) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986)). A fact is "material" if proof of its existence or nonexistence might affect the outcome of the litigation, and a dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248.

The Court views the facts in the light most favorable to the nonmoving party. "After making all reasonable inferences in the nonmoving party's favor, there is a genuine issue of material fact if a reasonable jury could find for the nonmoving party." Pignataro v. Port Auth., 593 F.3d 265, 268 (3d Cir. 2010). While the moving party bears the initial burden of showing the absence of a genuine issue of material fact, meeting this obligation shifts the burden to the nonmoving party who must "set forth specific facts showing that there is a genuine

issue for trial." Anderson, 477 U.S. at 250 (quoting Fed. R. Civ. P. 56).

IV. DISCUSSION

The motions before the Court will both be granted in part. Defendants' motion in limine will be granted in part and denied in part because Jackson's expert only uses reliable methods for one of his conclusions. Defendants' motion for summary judgment will be granted in part and denied in part because Jackson only presents sufficient evidence of a genuine dispute of material fact about River's Edge's submission of a legally false claim in its submission of inaccurate forms.

A. Motion in Limine

Defendants' motion in limine will be granted except to the extent it seeks to exclude testimony that River's Edge's submission of inaccurate MDS forms constitutes a false claim. Jackson offers an expert report by Craig Ratner, Esq., who holds a J.D., is certified in healthcare compliance, and was a compliance officer for Abington Jefferson Health. He spent three hours reviewing the thousands of pages of materials in this case before forming his opinions contained in the expert report.

Ratner opines that River's Edge submitted false claims to the government by (1) providing worthless services through

substandard care and (2) submitting false and inaccurate forms to the government. Ratner concludes that River's Edge provided worthless services because it failed to maintain adequate staffing, keep adequate supplies, and refer residents to specialists. And he concludes that River's Edge submitted false forms because the Pennsylvania Department of Health found River's Edge failed to submit accurate MDS forms and Jackson testified about errors in the ADL forms.

An expert's opinion is admissible if the expert's knowledge will help the jury understand evidence or determine a fact, the opinion is based on sufficient facts, the opinion is based on reliable principles and methods, and the principles and methods were reliably applied to the facts. Fed. R. Evid. 702. Ratner is qualified to testify as an expert on healthcare regulation compliance due to his experience and credentials in healthcare regulation compliance. His opinion will help the jury determine whether River's Edge complied with regulations, and his methods are reliably applied to the facts when he uses reliable methods. Although the three hours he spent reviewing materials appear to be barely adequate to review the voluminous record, he did collect sufficient data, and where his methodology is reliable, the opinion is based on sufficient facts. Thus, the analysis focuses on the reliability of his methodologies.

Whether an opinion is based on reliable principles and methods depends on a flexible inquiry into the principles and methods utilized. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (3d Cir. 1994). To determine the reliability of methods the Court "consider[s] multiple factors, including the testability of the hypothesis, whether it has been peer reviewed or published, the error rate, whether standards controlling the technique's operation exist, and whether the methodology is generally accepted." In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig., 858 F.3d 787, 792 (3d Cir. 2017).[4] These factors must show good grounds for the opinion; an opinion based on speculation or an educated guess is inadmissible. Ruggiero v. Yamaha Motor Corp., 778 F. App'x 88, 93 (3d Cir. 2019) (nonprecedential). And a failure to attempt a calculation that can be performed to verify the conclusion is sufficient to find that the opinion is merely speculation. See Oddi v. Ford Motor Co., 234 F.3d 136, 158 (3d Cir. 2000) (excluding an expert opinion where "[n]ot only did [the expert] not test his

[4] See also In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 n.8 (3d Cir. 1994) ("[The relevant factors include](1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.").

hypotheses, he did not even attempt to calculate" the relevant measurements to support his conclusions).

1. **Substandard and Worthless Services**

Ratner's opinion that River's Edge provided substandard care and worthless services in that it did not comply with the 2.7 hours PPD regulation will be excluded because his methodology is unreliable. In reaching the conclusion that River's Edge failed to comply with the PPD regulation, Ratner relies on the disparity between scheduled hours and payroll hours for one employee over a two-week period.[5] Between January 6, 2013, and January 20, 2013, one CNA was scheduled to work 90 hours, but the payroll reflected that she worked 77.5 hours. Based on this data, Ratner concludes that River's Edge could not have complied with the PPD regulation. Jackson fails to show how reviewing evidence that one employee did not work 12.5 hours scheduled over a two-week period is a reliable method to determine facility-wide compliance with PPD regulations.

This conclusion is inadmissible because Ratner did not make any calculation of the actual hours per patient based on the payroll records. Compliance with the PPD regulation is

[5] Although Ratner testifies that he reviewed materials for three employees, at his deposition he could only recall the details pertaining to one.

determined based on a calculation of actual hours worked as reflected in the payroll. Thus, the method of comparing the schedule to the payroll for a few employees over a short time is not reliable. Ratner needed to calculate the actual PPD based on the payroll for at least some period of time for his opinion to be reliable.[6] Ratner's opinion is based merely on speculation that because some workers sometimes called out or did not show up to work the facility was not in compliance with the PPD regulation. Thus, Ratner's opinion regarding worthless services is inadmissible.

2. Submission of Falsified and Fraudulent Documents

Ratner's opinion that River's Edge submitted falsified forms to the government is admissible because Pennsylvania Department of Health documents show that River's Edge submitted seven MDS forms with inaccuracies to the government. In forming this opinion, Ratner considered Jackson's testimony and Pennsylvania state records showing that River's Edge submitted seven MDS forms with inaccuracies to the government.[7] Given his

[6] Cf. Total Control, Inc. v. Danaher Corp., 338 F. Supp. 2d 566, 570 (E.D. Pa. 2004) ("Multiplication, of course, cannot be considered an unreliable method.").

[7] The Pennsylvania Department of Health documents also show that there were 12 cases of scabies not reported through the Electronic Event Reports required by Pennsylvania regulations. But because, as discussed below, there is no evidence that the accurate submission of these reports is material, these inaccurate submissions are irrelevant to liability such that Ratner's

expertise in healthcare compliance, Ratner's review of the documents showing the submission of inaccurate forms sufficiently supports his conclusion that the submissions of these forms constitute fraudulent or falsified submissions.[8]

But an opinion quantifying the number of inaccurate forms submitted is inadmissible to support a conclusion that the Defendants submitted other inaccurate forms beyond the seven forms identified by the Department of Health. Jackson testified that the ADL forms, which were used to create the MDS forms that went to the government, sometimes contained inaccuracies. From his review of this evidence, Ratner opines that Defendants submitted additional false and fraudulent forms to the government. But Ratner does not identify the methodology used to determine how many or whether there were any false MDS forms submitted as a result of ADL inaccuracies. Again, Ratner fails to perform any calculations, such as sampling or other statistical techniques, from which he could reliably extrapolate that the seven inaccurate forms reflected a greater number of

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testimony regarding these submissions would not be helpful to the jury. See infra Section IV.B.2.b.

[8] See In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741 (3d Cir. 1994) ("[T]he level of expertise may affect the reliability of the expert's opinion.").

inaccurate forms from the larger universe of forms submitted.[9] Thus, to the extent Ratner opines that there were more than seven false forms submitted, his opinion is inadmissible because he provides no reliable method used to reach this conclusion.

B. Motion for Summary Judgment

Defendants' motion for summary judgment will be granted except to the extent Jackson claims the submission of inaccurate forms constitutes the submission of a false claim. There is no genuine dispute that the services provided by River's Edge are not sufficiently substandard to constitute a factually false claim. But there is a genuine dispute about whether the inaccurate forms submitted to the government constitute a legally false claim.

The False Claims Act (FCA) allows suits by individuals, called relators, for frauds perpetuated on the United States. 31 U.S.C. § 3730(b), (d). The FCA holds liable any person who knowingly submits a false claim to the United States for payment. 31 U.S.C. §§ 3729–3730. To prevail on a False Claims Act claim, the plaintiff must establish that the defendant "(A) knowingly presents, or causes to be presented, a false or

[9] See U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 714 (7th Cir. 2014) (noting that statistical evidence may be used to prove the number of false MDS forms submitted).

fraudulent claim for payment or approval; [or] (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 94 (3d Cir. 2018) (alteration in original) (quoting 31 U.S.C. § 3729(a)(1)). Accordingly, the plaintiff must prove causation, falsity, scienter, and—at least where liability is based on a false certification—materiality. United States ex rel. Bookwalter v. UPMC, 946 F.3d 162, 175 (3d Cir. 2019); Greenfield, 880 F.3d at 94.[10]

The motion for summary judgment only contests two elements: falsity and materiality.

The falsity element "asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government." United States ex rel. Druding v. Care Alts., 952 F.3d 89, 97 (3d Cir. 2020). Claims under the False Claims Act may be either factually false or legally false. United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305 (3d Cir. 2011),

[10] See also United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 487 (3d Cir. 2017) (noting when discussing liability for a false certification that "[a] False Claims Act violation includes four elements: falsity, causation, knowledge, and materiality."); United States ex rel. Campie v. Gilead Scis., Inc., 862 F.3d 890, 902 (9th Cir. 2017) (noting that materiality is an element under a "factually false certification" theory).

abrogated on other grounds by Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016). A factually false claim "misrepresents what goods or services [were] provided to the Government," and a legally false claim "falsely certifies that [the claimant] has complied with a statute or regulation the compliance with which is a condition for Government payment." Id.

The materiality element asks "whether [the false certification] affected [the government's] payment decision." United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 492 (3d Cir. 2017). Materiality is an element of liability for a legally false claim. Greenfield, 880 F.3d at 94. And while materiality may also apply to factually false claims,[11] the Court does not address this issue because there is no genuine dispute of material fact about falsity for the factually false claims here.

1. Factually False and Worthless Services

The evidence Jackson has produced does not raise a genuine issue of fact that the services provided by River's Edge were

[11] See United States ex rel. Morgan v. Champion Fitness, Inc., No. 13-cv-1593, 2018 WL 5114124, at *8 (C.D. Ill. Oct. 19, 2018) ("The materiality standard may or may not apply in cases where factually false claims are alleged."); United States ex rel. Coffman v. City of Leavenworth, 303 F. Supp. 3d 1101, 1117 (D. Kan. 2018) ("Materiality is a requisite element for factually false claims under 31 U.S.C. § 3729(a)(1)(B) and false certification claims."), aff'd, 770 F. App'x 417 (10th Cir. 2019).

sufficiently substandard to constitute a factually false claim under the theory of worthless services. A claim is factually false when the service the government was billed for was not provided.[12] Wilkins, 659 F.3d at 305.[13] This includes when the service billed for was worthless in that it was so substandard that it was "tantamount to no service at all." In re Genesis Health Ventures, Inc., 112 F. App'x 140, 143 (3d Cir. 2004) (nonprecedential).[14] And a claim is factually false due to the provision of worthless services where a defendant sought "federal reimbursement for a procedure with no medical value." United States ex rel. Mikes v. Straus, 274 F.3d 687, 702 (2d Cir. 2001), abrogated on other grounds by Universal Health

[12] Jackson argues that there is a dispute of fact about whether River's Edge submitted claims for services that were not provided at all. This argument fails because Jackson does not point to a single claim submitted where the service was not provided at all. It is insufficient to provide evidence of arguably deficient operations and argue that there must have been a claim that was submitted where no services were rendered. See U.S. ex rel. Quinn v. Omnicare Inc., 382 F.3d 432, 440 (3d Cir. 2004) ("[Plaintiff's] theory that the claims 'must have been' submitted cannot survive a motion for summary judgment.").

[13] See also United States ex rel. Schimelpfenig v. Dr. Reddy's Labs. Ltd., No. 11-cv-4607, 2017 WL 1133956, at *3 (E.D. Pa. Mar. 27, 2017) ("In a run-of-the-mill factually false case . . . [a] relator must generally show that the [G]overnment payee has submitted an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." (quoting United States ex rel. Connor v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008) (alterations in original)).

[14] See also U.S. ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001) ("In an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under § 3729, regardless of any false certification conduct.").

Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016).

It is true that, under certain circumstances, under the theory of worthless services a claim can be maintained against a defendant that fails to comply with regulations that are intended to ensure that the services provided to the government have value. Under this theory, a defendant may be liable for noncompliance with a regulation that aims to prevent "Medicare waste, fraud, and abuse, i.e. paying out on claims that should not be paid." United States ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125, 158, 160, 166 (E.D. Pa. 2012). And a failure to comply with a regulation that informs the quality or the level of the service at issue can be the basis for a claim under a worthless services theory because "seriously deficient" service is akin to "a product that does not work." United States ex rel. Scharber v. Golden Gate Nat'l Senior Care LLC, 135 F. Supp. 3d 944, 965 (D. Minn. 2015).[15]

[15] See also Claire M. Sylvia, The False Claims Act: Fraud Against the Government § 4:34 ("A good or service that does not conform to a material contractual requirement may also be described as 'factually false' because the good or service delivered is not the product that was purchased."); cf. United States ex rel. Polansky v. Exec. Health Res., Inc., 196 F. Supp. 3d 477, 498–99 (E.D. Pa. 2016) (finding that the plaintiff did not adequately state a factually false claim where the falsity was based on a violation of a regulation that did not affect "the level, quality or scope of care.").

Under the standard of care provided by federal statutes and regulations, nursing homes "must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident." 42 U.S.C. § 1396r(b)(1)(A); accord 42 C.F.R. § 483.10(a)(1). They are required to "provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive assessment and plan of care." 42 C.F.R. § 483.24. So, in general and under certain circumstances, a nursing home that does not care for its residents in a way that promotes their quality of life may be liable under a worthless services theory.

That having been said, more than mere regulatory noncompliance is required for liability to attach; the noncompliance must be so great that effectively no services were provided. It is insufficient "that the defendant provided services that are worth some amount less than the services paid for" because "a 'diminished value' of services theory" does not exist. United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 710 (7th Cir. 2014). Instead, the provision of the services must be "so substandard as to be tantamount to no service at all." In re Genesis Health

Ventures, Inc., 112 F. App'x 140 at 143.[16] This heightened degree of noncompliance is required because the FCA is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations." Escobar, 136 S. Ct. at 2003.[17]

And a defendant provides effectively no services when it provides services that are grossly negligent with respect to the regulatory standard of care. There is a "proverbial line in the sand for purposes of determining when clearly substandard services become 'worthless.'"[18] United States v. Houser, 754 F.3d 1335, 1344 (11th Cir. 2014). And while no court of appeals has opined on where this line is drawn, the Court agrees with a number of district courts that have held that the line beyond

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[16] See Mikes, 274 F.3d at 703 ("In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all.").

[17] See Wilkins, 659 F.3d at 310 ("[W]e question the wisdom of regarding every violation of a Medicare regulation as a basis for a qui tam suit."); Chesbrough v. VPA, P.C., 655 F.3d 461, 468 (6th Cir. 2011) ("Quality-of-care issues were better monitored by state and local agencies and medical boards and societies than qui tam relators and the federal government.").

[18] The level at which services become worthless is a question of falsity, not scienter or materiality, because the question is not about the defendant's state of mind or the government's payment decision. See United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 491 (3d Cir. 2017) (noting the impropriety of conflating elements). The level of care deemed worthless is quintessentially a falsity issue because the inquiry is whether the service had no value to the government—i.e., the question is whether the claim was reimbursable. See United States ex rel. Druding v. Care Alts., 952 F.3d 89, 97 (3d Cir. 2020) ("[F]alsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government."); United States ex rel. Campie v. Gilead Scis., Inc., 862 F.3d 890, 900 (9th Cir. 2017) ("The value of the goods at issue is dispositive under the [worthless services theory.]").

which substandard services become worthless services is defined by gross negligence[19] in complying with standard of care regulations. See United States ex rel. Spay v. CVS Caremark Corp., No. 09-cv-4672, 2015 WL 5582553, at *63 (E.D. Pa. Sept. 22, 2015), aff'd on other grounds sub nom. United States ex rel. Spay v. CVS Caremark Corp., 875 F.3d 746 (3d Cir. 2017).[20] In other words, services provided without ordinary care will have some value to the government, but services provided without even slight care will have no value to the government.[21]

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[19] Gross negligence in general is the "lack of even slight diligence or care"; it is carelessness to a greater degree than ordinary negligence. Gross Negligence, Black's Law Dictionary (11th ed. 2019); see Dan B. Dobbs et al., The Law of Torts § 140 (2d ed. 2019) ("The term gross negligence can be used to mean what it says—a high, though unspecified degree of negligence, or as courts sometimes say, the failure to use even slight care.").

[20] See also United States ex rel. Acad. Health Ctr., Inc. v. Hyperion Found., Inc., No. 10-cv-552, 2014 WL 3385189, at *45 (S.D. Miss. July 9, 2014) (holding that "grossly deficient care" can form the basis for liability under the worthless services theory), report and recommendation adopted, 2017 WL 3260134 (S.D. Miss. July 31, 2017); United States ex rel. Spay v. CVS Caremark Corp., 913 F. Supp. 2d 125, 166 (E.D. Pa. 2012) ("A gross failure to perform such services, combined with continued collection of funds for such services from the government through the Part D sponsor, could constitute a false claim."); United States ex rel. Davis v. Prince, No. 08-cv-1244, 2011 WL 2749188, at *7 (E.D. Va. July 13, 2011) (explaining that the plaintiff would need to show that the defendant "'utterly failed' to perform [its] contractual duties" to succeed on a worthless services claim), aff'd sub nom. U.S. ex rel. Davis v. U.S. Training Ctr. Inc., 498 F. App'x 308 (4th Cir.2012) (nonprecedential); United States ex rel. Sanchez-Smith v. AHS Tulsa Reg'l Med. Ctr., 754 F. Supp. 2d 1270, 1287 (N.D. Okla. 2010) ("The Court holds that, in order to reach a jury on a factual falsity theory [the plaintiff must point to evidence of at least] the provision of grossly negligent services with regard to a particular standard of care or regulatory requirement." (citation omitted)).

[21] Services provided without ordinary care "creat[e] non-cost justified—wasteful or wealth-reducing—risks." Richard A. Posner, The Economics of Justice 84 (1983). It follows that services may be provided with such a lack of care—i.e., without even slight care—that the wasteful risks eclipse any benefit that may be conferred by the services. See Archie v. City of Racine, 847 F.2d 1211, 1219 (7th Cir. 1988) ("[G]rossly negligent[] mean[s] that the

The Seventh Circuit addressed the worthless services theory in the nursing home context in Absher, where it reversed a jury's verdict that awarded about $9 million to the plaintiffs. 764 F.3d at 705, 716. The plaintiffs presented evidence at trial that the defendant nursing home failed to prevent infections, control pests, manage pressure sores, provide correct medications, prevent accidents, and prevent staff abuse of residents. Id. at 705. But the defendant was never shut down despite state oversight, and one of the plaintiffs testified that a family member at the facility received good care. Id. at 710. The Seventh Circuit held that the defendant was entitled to judgment as a matter of law on the worthless services theory claim. Id. It reasoned that where the facility was allowed to continue to operate and one of the plaintiffs testified that a family member received good care, no reasonable jury could find that the defendant was providing worthless services. Id.[22]

In this case there is evidence of insufficient supplies, staffing shortages, and four negative incidents involving

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cost of taking precautions was substantially less than the expected benefits.").

[22] Cf. Acad. Health Ctr., Inc., 2014 WL 3385189, at *4, *43-45 (finding a plausible claim was stated under a worthless services theory where the state Department of Health found various "immediate jeopardy" deficiencies and the complaint alleged "heinous examples of grossly deficient care suffered by the seven representative residents").

River's Edge's residents. Although River's Edge received regular shipments of linens, Jackson claims that the linen supply was so insufficient that residents needed to be dried with pillow cases. And despite River's Edge's scheduling of staff to provide surplus hours, Jackson testifies that River's Edge was often short staffed such that each patient did not receive adequate care. She provides anecdotes about incidents with four residents—D.F., W.M., C.D., and an unidentified resident—as examples.

But, even in the light most favorable to Jackson, these incidents do not rise to the grossly negligent or significantly substandard care required to prove a claim under the worthless services theory. She claims that the care to each of these four residents was so poor that it constitutes worthless services. But no reasonable jury could conclude that the care to each of these residents was grossly negligent: D.F. was treated for scabies, W.M. was usually turned every two hours, C.D. was given emergency room treatment when she fell, and the patient with maggots in his wound had the maggots cleaned out. This treatment constitutes at least slight care to the promotion of quality of life, which precludes a finding of gross negligence.[23]

[23] Cf. Williams v. Terrace, No. 2856 EDA 2012, 2014 WL 10896964, at *7 (Pa. Super. Ct. July 31, 2014) (nonprecedential) (upholding a jury's finding

On an individual basis, each of the incidents described by Jackson at most rises to the level of negligence, i.e., failure to exercise ordinary care. Even assuming that the care was negligently given, this is not sufficient to allow a reasonable inference that there was a factually false claim through the provision of worthless services.[24] If an FCA claim could proceed on the basis of care rendered with ordinary negligence amounting to the provision of substandard care—as opposed to grossly negligent care amounting to significantly substandard care—the FCA would turn into a tool for ensuring regulatory compliance. But the Supreme Court has instructed that the FCA is not such a tool.[25] Therefore, the care which Jackson has identified as having been provided by River's Edge cannot form the basis for a factually false claim under the FCA.

Additionally, even if viewed cumulatively, and assuming that these incidents are representative of what is a more widespread problem at River's Edge regarding inadequate supplies, infection treatment and control, pressure sore

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that a nursing home's care was beyond grossly negligent where its "facilities were chronically and continuously understaffed," its resident suffering from bedsores was "routinely not repositioned" and died due to the bedsores, and there was "pervasive and routine[] failure[s] at [its] facilities").

[24] Indeed, Jackson herself describes the care she provided to these residents as fair, good, or excellent.

[25] See Escobar, 136 S. Ct. at 2004 ("We emphasize, however, that the False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations.").

treatment and control, and accident prevention, River's Edge's conduct does not rise to gross negligence. There is no evidence that these incidents were so pervasive that a reasonable inference of significantly substandard care can be drawn. River's Edge's processes for ensuring sufficient staffing, procuring supplies, and obtaining resident feedback all strongly point to finding that River's Edge is not grossly negligent in the care it provided to its residents. And like in Absher, the state Department of Health did not find any "immediate jeopardy" deficiencies that warranted disqualification in this case.[26]

2. Legally False

Summary judgment is appropriate on the implied certification theory but not on the express certification theory because Jackson only presents evidence of certifications in the form of inaccurate MDS forms. And even if Jackson did present other false certifications, she only points to evidence indicating that MDS forms are material.

[26] To the extent Jackson argues that the state authorities never found River's Edge's deficiencies because River's Edge moved staff around to ensure an adequate number of staff whenever there was a state inspection, this argument is belied by the Department of Health's inspections being unannounced. Further, an increase in staff during inspections does not account for the opportunity for residents to raise complaints with the Department of Health as a mechanism for the state agency to detect River's Edge's deficiencies.

A legally false claim is based on the defendant's false certification; i.e., it is where the defendant "lies about its compliance with a statutory, regulatory, or contractual requirement." United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 94 (3d Cir. 2018). And for liability to attach, the defendant's false certification "about its compliance with a legal requirement [must be] 'material to the Government's payment decision.'" Id. (quoting Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1996 (2016)).

a. False Certifications

A plaintiff may show a false certification through either an express certification or an implied certification. The false certification may be express in that the claimant affirmatively represents compliance with a statute or regulation with which it did not comply. United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 305 (3d Cir. 2011), abrogated on other grounds by Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016). Or the certification may be implied in that the claimant seeks payment without disclosing that it violated statutes or regulations. Id.

i. Express Certification

A reasonable jury could find that River's Edge submitted seven express false certifications because the Pennsylvania Department of Health found that River's Edge submitted seven inaccurate MDS forms. The submission of a false or inaccurate MDS form constitutes an express false certification because nursing home facilities must complete these documents and certify that they are accurate. United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 713 (7th Cir. 2014) (citing 42 C.F.R. § 483.20).

But a plaintiff must come forth with evidence that the defendant actually submitted a false claim. It is not enough to allege that, based on the scheme described, "claims requesting illegal payments must have been submitted, were likely submitted[,] or should have been submitted to the Government." Greenfield, 880 F.3d at 98 (alteration in original) (quoting United States ex rel. Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1311 (11th Cir. 2002)). So, while the submission of an inaccurate MDS form constitutes an express false claim, there must be evidence that a false MDS form was submitted. See Absher, 764 F.3d at 714 ("Rather, the relators have failed to offer evidence establishing that even a roughly approximate number of forms contained false certifications.").

A plaintiff cannot prevail on an express certification theory based on inaccurate MDS forms if it cannot show how many inaccurate MDS forms were submitted. In Absher, the plaintiffs produced evidence that there was a scabies outbreak and that not all residents were treated or diagnosed, that there were some months with no pressure ulcers reported and other months with many pressure ulcers reported, and that the defendant failed to track the development of rashes among residents. Id. at 713–14. They argued that from this evidence a jury could infer that there were inaccurate MDS forms submitted. Id. The Seventh Circuit held that this evidence failed as a matter of law because the plaintiff has the burden of proving how many claims were false. Id. at 714. It reasoned that a failure to offer evidence of at least a "roughly approximate" number of MDS forms containing false certifications constitutes a "fatal lack of evidence." Id. at 713-14.

Here, there is evidence of at least seven false claims in that seven MDS forms were submitted with inaccuracies. This evidence consists of the Pennsylvania Department of Health's conclusion that 7 of 22 MDS forms it reviewed were inaccurate. Although this evidence is sufficient to support a claim as to these seven MDS forms, it is insufficient to support an inference that some (or all) of the other forms submitted were

also inaccurate. Following Absher, Jackson's testimony that ADL forms were completed sometimes weeks after the care was given is not sufficient to show false claims were actually submitted. Therefore, the evidence is sufficient as to the seven inaccurate forms but not as to any of the other submitted forms. See Greenfield, 880 F.3d at 99 ("Our sister circuits have applied the same analysis, holding that plaintiffs must provide evidence of at least one false claim to prevail on summary judgment.").[27]

ii. Implied Certification

No reasonable jury could find that River's Edge submitted an implied false certification because Jackson does not point to any evidence showing that River's Edge made specific representations. An implied certification consists of (1) "specific representations about the goods or services provided" and (2) "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements." United

[27] To the extent Jackson argues that Medicare and Medicaid enrollment forms—specifically CMS Form 855A and CMS Form 1561—contained certifications that River's Edge would comply with all regulations, these promises cannot constitute false certifications unless there is some evidence that River's Edge knew it would not comply with the regulations when it made the promises. See United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 712 n.14 (7th Cir. 2014) ("A statement about one's present intent to perform some act in the future can be false. But the mere fact that the promised act is not subsequently performed does not necessarily mean that the promisor did not intend to perform the act at the time of making the promise."). However, Jackson does not point to evidence of such fraudulent inducement. Thus, based on the record, no reasonable jury could find that these certifications were fraudulent when made.

States v. Eastwick Coll., 657 F. App'x 89, 94 (3d Cir. 2016) (nonprecedential) (quoting Universal Health Servs. v. United States ex rel. Escobar, 136 S. Ct. 1989, 2001 (2016)).

Jackson argues that no specific representations are needed for an implied certification and that instead a submission for payment together with noncompliance with regulations constitutes an implied certification. While it is true that the Supreme Court in Escobar, 136 S. Ct. at 2000, left open the question of whether specific representations were always required for an implied false certification, the Third Circuit in Eastwick Coll., 657 F. App'x at 94, albeit in a nonprecedential opinion, suggested that an implied false representation "require[s] specific representations." United States ex rel. Schimelpfenig v. Dr. Reddy's Labs. Ltd., No. 11-cv-4607, 2017 WL 1133956, at *6 (E.D. Pa. Mar. 27, 2017).[28] And to the extent there is some doubt about the availability of an implied-certification-without-representation theory, the Third Circuit has found in a

[28] But see United States ex rel. Wood v. Allergan, Inc., 246 F. Supp. 3d 772, 811 (S.D.N.Y. 2017) ("[F]alsity may arise from the defendant's submission of a claim for payment that does not include a specific representation about the goods or services provided, coupled with noncompliance with a material payment requirement."), rev'd on other grounds, 899 F.3d 163 (2d Cir. 2018).

different situation that expansion of the implied certification theory is especially not appropriate in the healthcare context.[29]

b. Materiality

Finally, Jackson must also show that there is a genuine dispute of material fact that any false certifications were also material. Even if River's Edge had made false certifications regarding compliance with federal or state regulations, Jackson has not provided sufficient evidence to raise a genuine dispute of material fact that these certifications are material. On the other hand, there is a genuine dispute of material fact about whether a false certification based on an inaccurate MDS form is material.

Whether a false certification is express or implied, it must be "material to the Government's payment decision" for liability to attach. United States ex rel. Greenfield v. Medco Health Sols., Inc., 880 F.3d 89, 94 (3d Cir. 2018) (quoting Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1996 (2016)). The materiality "requirement helps ensure that the False Claims Act does not become 'an all-

[29] See United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 307 (3d Cir. 2011) ("As several courts of appeals have held, however, the implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs."), abrogated on other grounds by Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016).

purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract.'" United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 489 (3d Cir. 2017) (quoting Escobar, 136 S. Ct. at 2003).

Under the FCA "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). A false certification is material only if (1) "a reasonable man would attach importance to [it]" or (2) "the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter 'in determining his choice of action,' even though a reasonable person would not." Escobar, 136 S. Ct. at 2002–03 (quoting Restatement (Second) of Torts § 538 (1976)).

The materiality inquiry is holistic in that it considers all of the facts to determine "the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." Id. at 2002 (quoting 26 R. Lord, Williston on Contracts § 69:12 (4th ed. 2003)). Proof of materiality includes, but is not limited to, (1) evidence that the provision is expressly labeled a condition of payment and (2) evidence that the government consistently refuses to pay claims in cases

where the claimant did not comply with the provision. Id. at 2003.

Jackson argues that River's Edge made false certifications of compliance with four regulations: (1) Pennsylvania's PPD regulation, (2) Pennsylvania's Electronic Event Reports regulation, (3) federal standard of care regulations, and (4) federal MDS regulations. Jackson does not advance the materiality argument for each alleged false certification independently. Instead of disentangling the four alleged certifications and pointing to evidence of materiality for each, Jackson argues that the care provided was so poor and the regulations at issue so central to the public health program, that all of the alleged false certifications must be material.

As to the first three, no reasonable jury could find, looking at the evidence in the light most favorable to Jackson, that compliance with either Pennsylvania's PPD regulation, Pennsylvania's Electronic Event Reports regulation, or federal standard of care regulations is material. It is true that "[a] certificate of compliance with federal health care law is a prerequisite to eligibility under the Medicare program." United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d

Cir. 2004).[30] But Jackson has not provided any evidence that compliance with the federal standard of care or state regulations is a condition of payment, nor has she provided any evidence that the government has declined payment for failure to comply with these regulations.[31] And Jackson does not point to any other evidence indicating that these regulations are material.

That said, as to the fourth, Jackson does present evidence that accurate MDS forms are material in that the accuracy of MDS forms is an express condition of payment. MDS forms "specifically affirm that reimbursement is 'conditioned on the accuracy and truthfulness of [the] information' contained in the forms." U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc., 764 F.3d 699, 713 (7th Cir. 2014) (alteration in original). And payment per patient is based on the information contained in the MDS forms. So, a reasonable jury could find that submitting inaccurate MDS forms is material.

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[30] Indeed, the regulations require an annual certification saying the following: "I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations." 42 C.F.R. § 413.24(f)(4)(iv)(B).

[31] It is also relevant that the United States decided not to intervene in this action after having investigated it; this indicates that the violations alleged here are not material. Polansky v. Exec. Health Res., Inc., 422 F. Supp. 3d 916, 938 (E.D. Pa. 2019) ("Post-Escobar, numerous federal courts have found insufficient FCA materiality where the government investigated a relator's allegations but chose not to intervene or otherwise address the defendant's allegedly improper behavior.").

Thus, except for the MDS forms, Jackson has failed to raise a genuine dispute of fact that River's Edge's lack of compliance with federal or state requirements was material to the government's payment decision.

V. CONCLUSION

For the reasons set forth above, Defendants' motion in limine will be granted in part and denied in part and their motion for summary judgment will be granted in part and denied in part. An appropriate Order follows.